IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA

IN RE: FOSAMAX PRODUCTS LIABILITY
LITIGATION

MARY GUYANT

Civil Action No.:

Plaintiff,

v.

COMPLAINT AND
DEMAND FOR JURY TRIAL

1:07 -cv-1350-SEB-TAB

Plaintiff MARY GUYANT (alternatively referred to as "Plaintiff"), residing at 7740 Silver Fox Drive, Indianapolis, IN 46217 by and through her undersigned attorneys, hereby sues the defendant, MERCK & CO., INC., (hereinafter referred to as "Merck" or "Defendant"), which has its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100, and alleges as follows:

GENERAL BACKGROUND AND OVERVIEW OF CLAIMS

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling,

and/or sale of the pharmaceutical product known as Fosamax (hereinafter referred to as "Fosamax" or "the subject product").

- 2. At all times material hereto, Defendant designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold Fosamax for the prevention and treatment of osteoporosis as well as the treatment of Paget's disease.
- 3. As a result of the defective nature of Fosamax, those persons who were prescribed and ingested Fosamax, including Plaintiff, have suffered and continue to suffer severe and permanent injuries, including osteonecrosis of the jaw.
- 4. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.
- 5. Defendant knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.
- 6. Defendant failed to conduct adequate post-marketing surveillance of Fosamax after it began marketing, advertising, distributing and selling the product.
- 7. Consumers, including Plaintiff, who have used Fosamax for treatment of osteoporosis, have several alternative safer products available to treat this condition.
- 8. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.
 - 9. As a direct result, Plaintiff was prescribed and ingested Fosamax and has been

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permanently and severely injured. Plaintiff requires and will require ongoing medical care and treatment.

10. Consequently, Plaintiff seeks actual and punitive damages for her injuries resulting from her ingestion of Fosamax, which has caused and will continue to cause Plaintiff to suffer pain, mental anguish and other injuries, as well as to incur significant expenses.

JURISDICTION AND VENUE

- 11. This Court has jurisdiction pursuant to 28 United States Code §1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a citizen of the State of Indiana, and Defendant is incorporated and has its principal place of business in the State of New Jersey. The amount in controversy exceeds Seventy Thousand (\$75,000.00) Dollars, exclusive of interest and costs. Venue in this action properly lies in the Southern District of Indiana, Indianapolis, pursuant to 28 U.S.C. §1391 since Plaintiff resides, used Fosamax and was injured in this district.
 - 12. Venue is proper pursuant to Ind. T.R. 75(A)(4).
- 13. Accordingly MARY GUYANT, resident of Marion County, State of Indiana, hereby file this complaint against MERCK & CO., INC. directly in the Federal Southern District of Indiana, as a matter of convenience only.

PARTIES

- 14. Plaintiff MARY GUYANT is a resident of the City of Indianapolis and State of Indiana.
- 15. The Defendant, Merck & Co., is a New Jersey corporation, which has its principal place of business in Whitehouse, New Jersey.
 - 16. At all times material hereto, the Defendant, Merck & Co., was engaged in the

business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Fosamax.

- 17. Defendant is, and was at all relevant times, duly authorized to conduct business in the State of New York.
 - 18. Defendant, either directly or through its agents, servants, and employees, regularly solicits and transacts business within the State of New York.
- 19. Defendant, at all relevant times, has sold and distributed Fosamax in the State of New York for use in the treatment of osteoporosis or the prevention of osteoporosis.
- 20. Defendant derives substantial revenue from goods used or consumed in the State of New York.
- 21. Defendant expected, or should have expected, that its actions could or would have consequences within the State of New York.

SUBSTANTIVE ALLEGATIONS

- 22. In September 1995, Fosamax was approved for marketing and sale in the treatment of osteoporosis and Paget's disease.
- 23. Fosamax falls within a class of drugs known as bisphosphonates, which are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.
- 24. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphophonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate

(Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The Physician's Desk Reference ("PDR") listing for Fosamax confirms that the molecule contains a nitrogen atom.

- 25. Recent studies report the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy
- 26. Shortly after Defendant began selling Fosamax, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates.
- 27. Merck knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosponates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
- 28. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can develop into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).
- 29. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.
- 30. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

- 31. Since Fosamax as was released, the FDA has received a number of reports osteonecrosis of the jaw among users of Fosamax.
- 32. On August 25, 2004, the United States Food and Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (Fosamax). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaulation.
- 33. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, Fosamax.
- 34. As a result, the FDA recommended and stated that the labeling for Fosamax should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw.

 Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in it's Fosamax labeling in the warnings section.
- 35. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendant continues to defendant Fosamax and minimize unfavorable findings.
- 36. Fosamax is one of Defendant's top selling drugs, which average more than \$3 billion a year in sales.
 - 37. As with its reported and acknowledged side effects concerning irritation,

erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have know that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other nitrogenous bisphosphonates.

- 38. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax -D, and sought to extend the exclusivity period of Fosamax through 2018.
- 39. Fosamax remains in the body for years after ingestion but provides minimal benefits for preventing bone fractures. Additionally, if taken over long periods of time, the drug can make bones more brittle and increase the risk of fracture.
- 40. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient taking Fosamax.
- 41. Rather than warn patients and the medical community, and despite knowledge by Defendant of increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendant continued and continues to defend and aggressively market Fosamax, while downplaying any unfavorable findings and overstating its benefits.
- 42. Fosamax is now the world's top-selling bisphosphonate and Defendant's second-best selling drug, with more than 22 million prescriptions in 2005 amounting to \$3.2 billion in sales.

Plaintiff's Use of Fosamax

43. Plaintiff MARY GUYANT was prescribed and took Fosamax from in or about 1998 through 2004.

- 44. Plaintiff used Fosamax as prescribed and for the purpose and in the manner for which it was normally intended.
- 45. Plaintiff could not by the exercise of reasonable care discover the defective nature and perceive the danger of Fosamax.
- 46. As a direct and proximate result of using Fosamax, Plaintiff was diagnosed with necrotic bone of the jaw and other substantive jaw problems.
- 47. Plaintiff, as a direct and proximate result of using Fosamax, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.
- 48. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug.

EQUITABLE TOLLING OF APPLICABLE STATUES OF LIMITATIONS

- 49. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her prescribing physician the true risks associated with taking Fosamax.
- 50. As a result of Defendant's actions, Plaintiff and, upon information and belief, her prescribing physician were unaware, and could not reasonably know or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.
 - 51. Furthermore, Defendant is estopped from relying on any statue of limitations

because of their fraudulent concealment of the true character, quality and nature of Fosamax.

Defendant was under a duty to disclose the true character, quality and nature of Fosamax because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to the plaintiffs, medical providers and/or to their facilities. In addition, the Defendant is estopped from relying on any statue of limitations because of their international concealment of these facts.

52. The Plaintiff had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendant's representations.

FIRST CAUSE OF ACTION Negligence

- 53. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 54. Defendant had a duty to consumers, including Plaintiff, to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.
 - 55. Defendant failed to exercise due care under the circumstances, and therefore

breached its duty to Plaintiff.

- 56. Defendant's negligent acts and omissions, either directly or through its agents, servants, and employees, include, but are not limited to the following:
 - a. Manufacturing, producing, promoting, formulating, creating, and/or designing Fosamax without thoroughly and/or adequately testing it;
 - b. Not conducting sufficient testing programs to determine whether or not Fosamax was safe for use; in that Defendants herein knew or should have known that Fosamax was unsafe and unfit for use by reason of the dangers to it's users.
 - c. Selling Fosamax without making proper and sufficient tests to determine the dangers to it's users;
 - d. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Fosamax;
 - e. Negligently advertising and recommending the use of Fosamax with sufficient knowledge as to its dangerous propensities;
 - f. Negligently representing that Fosamax was safe for use for its intended purpose, when, in fact, it was unsafe;
 - g. Negligently designing Fosamax in a manner which was dangerous to its users;
 - h. Negligently manufacturing Fosamax in a manner which was dangerous to its users;
 - i. Negligently producing Fosamax in a manner which was dangerous to its users;

- j. Designing, manufacturing, marketing, advertising, distributing, and selling Fosamax to consumers, including Plaintiff, without an adequate warning of the dangerous risks of Fosamax and without proper instructions to avoid harm caused by Fosamax;
- k. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals and/or the FDA, concerning the severity of risks and dangers of Fosamax.
- Failing to exercise due care when advertising and promoting Fosamax;
 and;
- m. Failing to exercise ordinary care by conducting appropriate postmarket testing and surveillance of Fosamax.
- n. Defendants under-reported, underestimated and downplayed the serious dangers of Fosamax.
- 57. Although Defendant knew, or should have known, of Fosamax's adverse effects Defendant has continued to negligently manufacture, market, advertise, distribute, and sell Fosamax to consumers, including Plaintiff, so as to maximize sale and profits at the expense of public health and safety in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.
- 58. Defendant knew, or should have known, that consumers, including Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary care.
- 59. As a direct and proximate result of the Defendant's negligence and other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION

Strict Liability - Failure to Warn

- 60. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 61. Defendant designed, tested, manufactured, marketed, sold and/or distributed Fosamax. As such, it had a duty to warn the using public, including Plaintiff, of the health risks associated with using the subject product.
- 62. The subject product was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities of Defendant further diluted or minimized the warnings given with the product.
- 63. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw. Even though Defendant knew or should have known of the risks and reactions associated with the subject product, it still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.
- 64. Plaintiff used the subject product for its intended purpose, i.e. for the prevention or treatment of osteoporosis.

- 65. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.
- 66. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug.
- 67. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the subject product.
- 68. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her.
- 69. Defendant had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with the subject product. By negligently and/or wantonly failing to adequately warn of the dangers of use of the subject product, Defendant breached its duty.
- 70. Although Defendant knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by the subject product.
- 71. As a direct and proximate result of the Defendant's failure to adequately warn or other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION Strict Liability – Defective Design

- 72. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 73. Defendant is the manufacturer, seller, distributor, marketer, and/or supplier of the subject product, which is defective and unreasonably dangerous to consumers.
- 74. The subject product was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
- 75. The subject product was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.
- 76. Consumers, including Plaintiff, who have used Fosamax for the prevention or treatment of osteoporosis, have several alternative safer products available to treat this condition.
- 77. Although Defendant actually knew of the defective nature of the subject product, it continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.
- 78. As a direct and proximate result of the design defects of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory

and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION

Breach of Express Warranty

- 79. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 80. Defendant expressly represented to Plaintiff MARY GUYANT, other consumers and the medical community that Fosamax was safe and fit for its intended purposes, of merchantable quality, did not produce any dangerous side effects, and was adequately tested.
- 81. Fosamax does not conform to Defendant's express representations because it is defective and unfit for its intended purpose, i.e. it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.
- 82. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw.
- 83. At all relevant times Fosamax did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
- 84. Plaintiff MARY GUYANT, other consumers and the medical community relied upon Defendant's express warranties.
- 85. As a direct and proximate result of Defendant's express warranties of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION **Breach of Implied Warranty**

- 86. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 87. Defendant designed, tested, manufactured, marketed, sold and/or distributed Fosamax.
- 88. At all relevant times, Defendant knew of the use for which Fosamax was intended and impliedly warranted the product to be safe and fit for such use.
- 89. Defendant was aware that consumers, including Plaintiff, would use Fosamax for the prevention or treatment of osteoporosis, and knew, or recklessly disregarded, that consumers, including Plaintiff, and the medical community relied upon its judgment and sensibility to only sell Fosamax if it was safe and fit for its intended use.
- 90. Defendant herein breached its implied warranty to consumers, including Plaintiff; Fosamax was not safe or fit for its intended use.
- 91. Consumers, including Plaintiff, and the medical community reasonably relied upon Defendant's implied warranty for Fosamax.
- 92. Fosamax reached Plaintiff without substantial change in the condition in which it was manufactured and sold by Defendant.
 - 93. As a direct and proximate result of Defendant's implied warranties of the

subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION

Common Law Fraud

- 94. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 95. Defendant falsely and fraudulently represented to the medical community, and to the Plaintiff and the public in general, that Fosamax had been tested and found to be safe and effective for the prevention and treatment of osteoporosis.
- 96. Defendant knew, or should have known, that its representations were false yet it willfully, wantonly and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of Fosamax to consumers, including Plaintiff, and the medical community.
- 97. Defendant's representations were made with the intent of defrauding and deceiving consumers, including Plaintiff, and the medical community, with the intent of encouraging and inducing sales of Fosamax.
- 98. Defendant knowingly, consciously, and deliberately placed its financial gain above the rights and safety of Plaintiff and other consumers.
- 99. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

- 100. Plaintiff was unaware of the falsity of Defendant's representations and reasonably relied upon Defendant's representations, thereby developing osteonecrosis of the jaw.
- 101. As a direct and proximate result of Defendant's fraudulent misrepresentation of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION Fraudulent Concealment

- 102. Plaintiffs reallege the above paragraphs.
- 103. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:
 - a. Defendant represented through it's labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and
 - b. Defendant represented FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

EIGHTH CAUSE OF ACTION **Punitive Damages**

104. The foregoing paragraphs of this Complaint are realleged and incorporated

by reference.

- 105. Although Defendant knew or recklessly disregarded the fact that the subject product causes debilitating and potentially lethal side effects, Defendant continued to market the subject product to consumers, including Plaintiff, without disclosing these side effects.
- 106. Defendant knew of the subject product's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the subject product.
- 107. Defendant intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of the subject product to ensure their continued and increased sales. This intentional and/or reckless failure to disclose information deprived Plaintiff of the information necessary for her to weigh the true risks of using the subject product against the benefits.
- 108. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendant and it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION Negligence Per Se

109. Plaintiff repeats, reiterates and realleges each and every allegation of this

Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

- 110. Defendants have an obligation not to violate the law.
- 111. Defendants have violated the Federal Food, Drug and Cosmetic Act, 21, U.S.C. 301, et Seq., related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws.
- 112. Plaintiff, as a purchaser and consumer of Fosamax, is within the class of persons that statues described above are designed to protect.
- 113. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, misleading products and as otherwise set forth in this complaint, is the specific type of harm these statutes are designed to prevent.
- 114. Defendants are responsible to plaintiff for injuries incurred for their violations of the statutes described above under the doctrine of negligence pro se.
- the defendants and each one individually and as a result of the defendants' actions and/or inactions as set forth in this complaint, Plaintiff was caused to suffer the serious and dangerous side effect of osteonecrosis, as well as other severe and personal injuries which are permanent and lasting in nature, including but not limited to physical pain and mental anguish, diminished enjoyment of life, and any and all life complications such as Plaintiff's need for lifelong medical treatment, monitoring and/or medications, and to incur related expenses, including but not limited to, loss of earnings and/or other costs as the proof will demonstrate, and the plaintiff demands all damages to which the plaintiff is entitled under the law in an amount deemed fair and reasonable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendant as follows:

- a. That Plaintiff be granted and recover actual and compensatory damages incidental to her purchase and use of Fosamax in an amount to be determined at trial;
 - b. That Plaintiff be granted and recover treble and punitive damages;
 - c. That Plaintiff be granted pre-judgment and post-judgment interest;
 - d. That the costs of this action be taxed to Defendant;
- e. That Plaintiff be granted reasonable attorneys' fees and costs as provided by law; and
 - f. For such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

The Plaintiff demands a trial by jury on all issues.

Dated: October 18, 2007.

Respectfully Submitted,

TOV DE, 197350 W & DEE 15, EEC

Robert T. Dassow, #15145-64 10585 N. Meridian Street, Suite 205 Indianapolis, IN 46290 317.818.3100 tel.

Attorney for Plaintiff

Court Mane: Southern District of Indiana Division: I Receipt Humber: IP803921 Cashier ID: tanderso Transaction Date: 18/19/2007 Payer Hame: HOVDE DASSOW DEETS LLC

CIVIL FILING FEE
For: HOVDE DASSON DEETS LLC
Case/Party: D-INS-1-07-CV-001359-901
Amount: \$350.00

CHECK Check/Money Order Hum: 11224 Amt Tendered: \$350.00

Total Due: \$350.00 Total Tendered: \$350.00 Change Amt: \$8.00 Change Amt:

HOVDE DASSON & DEETS LLC

19585 M. Meridian St., Suite 295

Indianapolis, IN 46298

1:07-cv-1350-SEB-TAB

"Only when bank clears the check, woney order, or verifies credit of funds is the fee or debt officially paid or discharged. A \$45.00 fee will be charged for a returned check." SAO 440 (Rev. 10/93) Summons in a Civil Action

SAO 440 (Ref. 1073) Summons in a Civil Action				
UNITED STATES DISTRICT COURT				
SOUTHERN	District of	INDIANA		
MARY GUYANT V.	-	SUMMONS IN A CIVIL CASE		
MERCK & CO., INC.	CASE NUM	BER:		
		-cv-1350-SEB-TAB		
TO: (Name and address of Defendant)				
MERCK & CO., INC. c/o CT CORPORATION (Registered Agent) ONE NORTH CAPITOL INDIANAPOLIS, IN 46204				
YOU ARE HEREBY SUMMONED and requ	ired to serve upon PL	AINTIFF'S ATTORNEY (name and address)		
Robert T. Dassow HOVDE DASSOW & DEETS, LLC 10585 N. Meridian Street, Suite 205 Indianapolis, IN 46290				
an answer to the complaint which is herewith served summons upon you, exclusive of the day of service. I relief demanded in the complaint. You must also file 207 Federal Building,30 North Seventh Street, Terr	f you fail to do so, jud your answer with the	Clerk of this Court, Terre Haute Division		
CLERK CLERK	DATE	OCT 1 9 2007		

SAO 440 (Rev. 10/93) Summons in a Civil Action

RETURN OF SERVICE				
Service of the Summons and complaint was made by me ⁽¹⁾				
NAME OF SERVER (PRINT) TITLE				
Check	one box below to indicate appropriate	method of service		
	☐ Served personally upon the defendant. Place where			
	Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.			
	Name of person with whom the summons	and complaint		
	Returned			
√	Other Certified Mail			
		STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES		TOTAL	
		DECLARATION OF SERVER		
	contained in the Return of Service and Sta		ea that the foregoing information	
	Date Sig	gnature of Server		
	Aa	ldress of Server		

_ SAO 458 (Rev. 10/95) Appearance		Us Phyliad		
UNITED STA	TES DISTRICT COURT	2207 OCT 19 PH 4: 05		
SOUTHERN	DISTRICT OF INDIANA	A LACTION AND THE		
MARY GUYANT	APPEAR	ANCE		
Plaintiff,	Case Number:			
vs.				
MERCK & CO., INC., Defendant.	1 :07 -cv-135	O-SEB-TAB		
To the Clerk of this court and all parties	of record:			
Enter my appearance as counsel in this case for				
М	ARY GUYANT			
I certify that I am admitted to practice in this court. 10-18-07 Date Signature				
	Robert T. Dassow Print Name	#15145-64 Bar Number		
	10585 N. Meridian Stree	et, Suite 205		

<u>Indianapolis</u> City

317.818.3100 Phone Number IN State 46290 Zip Code

317.818.3111 Fax Number

AO 85 (modified by USDC IN-SD 6/03) Notice, Consent, a	and Order of Referen	nce — Exercise o	f Jurisdiction	by a United States M	Magistrate Judge
Unit	ED STATE	S DISTRI	ст Соц	JRT	
	Di	istrict of			
Plaintiff		NOTICE, CONSENT, AND ORDER OF REFERENCE — EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE			
V.		Case Nur	mber:		
Defendant	1	:07	-CV-	1350-	SEB-TAB
NOTICE OF AVAILABI	LITY OF A TO EXERCISE			1 agistrat	E JUDGE
In accordance with the provisions o magistrate judge of this district court is availa and to order the entry of a final judgment. Exparties voluntarily consent.	ble to conduct	any or all pro	ceedings i	n this case inclu	iding a jury or nonjury trial
You may, without adverse substantive from being exercised by a magistrate judge. It consent will not be communicated to any mag	f any party with	holds consen	it, the ident	ity of the partie	s consenting or withholding
An appeal from a judgment entered by this judicial circuit in the same manner as an a					ed States court of appeals for
CONSENT TO THE EXERCISE OF	JURISDICT	TION BY A	United	STATES M	agistrate Judge
In accordance with provisions of 28 U States magistrate judge conduct any and all proceedings.				•	
Party Represented		Sign	atures		Date
	ORDER O	F REFERE	ENCE		
IT IS ORDERED that this case be read and order the entry of judgment in accordance					to conduct all proceedings
Date		United	States District	Judge	

NOTE: RETURN THIS FORM TO THE CLERK OF THE COURT <u>ONLY IF</u> ALL PARTIES HAVE CONSENTED <u>ON THIS FORM</u> TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE.

United States District Court				
SOUTHERN	District of	INDIANA		
MARY GUYANT V.		SUMMONS IN A CIVIL CASE		
MERCK & CO., INC.	CASE NU	MBER: 1:07-CV-1350-SEB-TAB		
TO: (Name and address of Defendant)				
MERCK & CO., INC. One Merck Drive P.O. Box 100 Whitehouse Station, NJ 08889-0100				
YOU ARE HEREBY SUMMONED and requ	nired to serve upon P	PLAINTIFF'S ATTORNEY (name and address)		
Robert T. Dassow HOVDE DASSOW & DEETS, LLC 10585 N. Meridian Street, Suite 205 Indianapolis, IN 46290				
an answer to the complaint which is herewith served summons upon you, exclusive of the day of service. I relief demanded in the complaint. You must also file 207 Federal Building, 30 North Seventh Street, Terminal Street, Termi	If you fail to do so, je your answer with	the Clerk of this Court, Terre Haute Division		
CLERK CLERK	DATE	NOV 0 5 2007		

≈ AO 440	(Rev. 10/93)	Summons in a Civil Action	

RETURN OF SERVICE				
Service of the Summons and complaint was made by me ⁽¹⁾				
NAME OF	SERVER (PRINT)	TITLE		
Check	Check one box below to indicate appropriate method of service			
	☐ Served personally upon the defendant. Place where			
	☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.			
	Name of person with whom the summons	and complaint		
	Returned			
√	Other <u>Certified Mail</u>			
		STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES		TOTAL	
		DECLARATION OF SERVER		
	contained in the Return of Service and Star	runder the laws of the United States of Americatement of Service Fees is true and correct.	ca that the foregoing information	
	Ad	dress of Server		

Case 1:07-cv-10471-JFK

Page 1 of 2 JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

OCT 3 0 2007

CV 10471

FILED CLERK'S OFFICE

UNITED STATES JUDICIAL PANEL MULTIDISTRICT LITIGATION

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

Mary Guyant v. Merck & Co., Inc., S.D. Indiana, C.A. No. 1:07-1350

NOV 25 2007

CONDITIONAL TRANSFER ORDER (CTO-38)

)

U.S. CLERK'S OFFICE INDIANAPOLIS, INDIANA

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. See 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 101 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the action on this conditional transfer order involves questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), this action is transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Inasmuch as no objection is pending at this time, the stay is lifted.

NOV 1 5 2007

CLERK'S OFFICE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION A CERTIFIED COPY

Clerk of the Panel

J. MICHAEL McMAHON,

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

MDL No. 1789

INVOLVED COUNSEL LIST (CTO-38)

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